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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,796	06/11/2001	Patricia De Jong	B0-42260	9646
466	7590	01/05/2004	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			HENDRICKS, KEITH D	
			ART UNIT	PAPER NUMBER

1761

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,796

Applicant(s)

DE JONG ET AL.

Examiner

Keith Hendricks

Art Unit

1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 14-26 are currently pending. Claims 27-55 have been canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the utilization of lactic acid bacteria (including *Bifidobacterium* strains) and *Saccharomyces* yeast, does not reasonably provide enablement for the use of any random type of bacterial strain or yeast strain, as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification provides support for the use of certain types of bacteria, namely lactic acid bacteria, and for the use of *Saccharomyces* strains of yeast, but does not provide support for the use of any of the millions of other types and strains of bacteria or yeast that are known. The specification does not provide sufficient guidance required for keeping any and all types of bacteria and yeast viable, outside of the genus/species specifically recited and/or demonstrated in the specification. A number of factors must be considered in assessing the enablement of an invention, including the following: the breadth of the claims, the amount of experimentation necessary, the guidance provided in the specification, working examples provided, predictability, and the state of the art. See *In re Wands*, 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Circ. 1988). Given these factors, the specification does not provide the guidance and enablement necessary to utilize any random type of bacteria or yeast, outside of those particularly noted above and in the specification, as each type of these organisms require vastly different modes of culturing and production for use, many of which cannot be made stable for use in food systems, especially in dried form, as claimed. Furthermore, only certain types of bacteria, such as the lactic acid bacteria described in the specification, would be able to utilize the oligosaccharides provided in the nutritional supplement, and in the amounts claimed, which is the stated purpose of including said oligosaccharides.

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Note that claim 23 is included in the rejection, as it recites that "at least one of the bacterial strains comprises one or more strains of a *Lactobacillus* or one or more strains of a *Bifidobacterium* species". This claim language encompasses the use of strains of bacteria other than *Lactobacillus* or *Bifidobacterium*, and thus is included in the rejection.

Conclusion


For the record, it is noted that applicants' claims recite the use of "oligosaccharides", which, according to page 2 of the specification, "these oligosaccharides as a rule have a degree of polymerisation [sic] of 2 to 20." Thus, while the use of monosaccharides and/or polysaccharides (i.e. with a DP of greater than 20) is additionally encompassed, the claimed nutritional supplement must contain at least 40-80 weight % of oligosaccharides which are also non-digestible by humans. As correctly stated by applicants in the response of September 22, 2003, the prior art of record does not utilize or suggest the claimed requisite elements in this regard, namely oligosaccharides that are both (a) present in amounts of 40-80% by weight, and (b) non-digestible by humans. Reference is also made to WO 96/26732 (Ronchi et al., of record), which teaches nutritional compositions comprising one or more strains of lactic acid bacteria and *Saccharomyces* lysates (i.e. dead, lysed yeast cells) in combination with vegetable-derived glucans. However, the glucans are polysaccharides, which are larger than oligosaccharides, are not sufficiently hydrolyzed, and are thus not encompassed by the instant claims. Exemplified glucans include microcrystalline cellulose (DP 100+), or lactose or saccharose (sucrose), both of which are digestible by humans.

Therefore, the claims are free of the prior art of record, and would be allowable if re-written to overcome the 112, 1st paragraph rejection above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-0987.


KEITH HENDRICKS
PRIMARY EXAMINER